CALIFORNIA Prostate Cancer COALITION

"Fighting Prostate Cancer in California!"

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NEWS

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PRESIDENT'S MESSAGE

I wish a Happy New Year to all. I hope that 2013 brings good health and that we make great strides in prostate cancer diagnosis and treatment, as well as in survivorship and quality of life.

Fall was a busy time. I attended the European Multidisciplinary Urologic Cancers Meeting (EMUC) in November at which there was no talk whatsoever on whether to test men for prostate cancer, but rather an emphasis on avoiding starting hormonal therapy prematurely and making men castrate-resistant too early. This is an interesting twist and it is refreshing not to hear whether or not we should be using PSA.

I also participated in the National Comprehensive Cancer Network Meeting on Advocacy in Washington, DC and the Society of Urologic Oncology (SUO) meeting in Bethesda, MD shortly afterwards. One presenter, Ruth Etzione, is a statistician upon whose data the US Preventive Services Task Force (USPSTF) had partially relied when drafting its "D" Recommendation against PSA testing. Her presentation showed that USPSTF had incorrectly summarized the data she provided to them. Of note, this new data was published as an online manuscript in December, an abstract of which appears on page 3 of this newsletter. With this new information available, CPCC takes the position that the USPSTF should reconsider their "D" recommendation regarding the value of early detection of prostate cancer using PSA.

I then attended the Prostate Cancer Roundtable Meeting in Washington, DC where we had a full discussion on our policy agenda for 2013. That includes continuing our efforts to sway USPSTF, supporting legislation that would change the make-up and requirements for consultation of the USPSTF, and working on the Affordable Health Care Act as it will impact prostate cancer patients in various states.

On January 29th we held our Annual Face-to-Face Board Meeting in Daly City. We nominated new Board Members and crafted our Strategic Plan for 2013. Please let us know if you are interested in getting involved in CPCC or in working on any of our Committees. Every bit of help is appreciated!

Respectfully submitted,
MEREL GREY NISSENBERG

HOW PROSTATE CANCER THERAPIES COMPARE BY COST AND EFFECTIVENESS

The most comprehensive retrospective study ever conducted comparing how the major types of prostate cancer treatments stack up to each other in terms of saving lives and cost effectiveness for localized prostate cancer was reported by a team of researchers at the University of California, San Francisco (UCSF).

Localized prostate cancer accounts for about 81 percent of the quarter-million prostate cancers diagnosed in the US every year, according to the National Cancer Institute. It is defined by tumors that have not metastasized and spread outside the prostate gland to other parts of the body.

Published online ahead of print in the *British Journal of Urology International*, the work analyzed 232 papers published in the last decade that reported clinical results in men with low-, intermediate- and high-risk forms of prostate cancer who were treated with one or more standard treatments – radiation therapy (RT), radical prostatectomy (RP), androgen deprivation therapies (ADT) and brachytherapy (BT). A limitation of the study is that it did not consider two other available approaches – active surveillance (AS) and proton beam therapy.

There are variations of each treatment – open, laparoscopic or robot-assisted RP; dose-escalated 3-dimensional conformal RT, intensity-modulated RT and BT; various ADT regimens; and combinations of these. Many men with low-risk disease do not need any of these treatments and can safely undergo AS, at least initially.

The analysis shows that for men with low-risk prostate cancer, the odds of survival vary only slightly between the various treatments, with reported 5-year cancer-specific survival rates of nearly 100 percent. But the cost of RT is significantly more expensive than RP for low-risk prostate cancer, they found.

For intermediate- and high-risk cancers, both survival and cost generally favored RP over other treatments – although external-beam RT and BT combined were comparable in terms of quality of life-adjusted survival for high-risk prostate cancer.

"Our findings support a greater role for surgery for high-risk disease than we have generally seen it used in most practice settings," said urologist Matthew Cooperberg, MD, MPH who led the research. Cooperberg is an

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BAYER SUBMITS NEW DRUG APPLICATION FOR RADIUM (RA-223 DICHLORIDE) FOR THE TREATMENT OF CASTRATION-RESISTANT PROSTATE CANCER (CRPC) WITH BONE METASTASES

Bayer HealthCare announced in December 2012 that the company has submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) seeking approval for radium-223 dichloride (radium-223), an investigational compound for the treatment of castration -resistant prostate cancer (CRPC) with bone metastases.

"Radium-223 (proposed trade name Alpharadin) was granted fast track designation by the FDA. The fast track process is designed to facilitate the development and expedited review of drugs to treat serious diseases and fill an unmet medical need. Fast track designation must be requested by the drug company and can be initiated at any time during the drug development process.

The submission was based on data from the ALSYMPCA (ALpharadin in SYMptomatic Prostate CAncer) trial, a Phase III, randomized, double-blind, placebo-controlled international study of radium-223 with best supportive care (BSC) vs. placebo with BSC in symptomatic CRPC patients with bone metastases. The trial enrolled 921 patients in more than 100 centers in 19 countries. The study treatment consisted of up to six intravenous administrations of radium-223 or placebo each separated by an interval of four weeks.

The primary endpoint of the study was overall survival (OS). Secondary endpoints included time to occurrence of skeletal-related events (SRE), time to total alkaline phosphatase (ALP) and PSA progression, total ALP response and normalization, safety, and quality of life. Data was presented in June 2012 at the 48th Annual Meeting of the American Society of Clinical Oncology.

Although not covered in this Company news release, updated trial results showed that radium-223 significantly increased OS (HR=0.695, P=0.00007). The median OS benefit in men given radium-223 dichloride increased from 2.8 months at the time of the pre-planned interim analysis in June 2011 to 3.6 months in an updated analysis a year later [14.9 months in the radium-223 dichloride group plus BSC vs. 11.3 months with placebo plus BSC]. In addition to improving OS, radium-223 dichloride led to a statistically significant delay in the time to first SRE.

The overall safety and tolerability profile for radium-223 dichloride was consistent with previous study results. The most common hematologic adverse events for patients receiving radium-223 dichloride as compared to placebo included anemia, neutropenia and thrombocytopenia. The most common non-hematologic adverse events more common included bone pain, nausea, diarrhea and vomiting.

"If approved, radium-223 has the potential to play a key role in the treatment of men with CRPC that has metastasized to the bone," said Pamela A. Cyrus, MD, Vice President and Head of US Medical Affairs, Bayer HealthCare Pharmaceuticals. "The development of a compound like radium-223 is an example of Bayer's commitment to investing in approaches to treat hard-to-treat cancers."

Radium-223 is an investigational agent and is not approved by the FDA, the European Medicines Agency (EMA), or other health authorities.

Bayer Healthcare News Release
14 December 2012

VALUE OF TRANSRECTAL POWER DOPPLER SONOGRAPHY FOR DETECTING LOW RISK PROSTATE CANCERS

Sauvain JL, Sauvain E, Rohmer P, et al

Diagn Interv Imaging, 1 December 2012, Epub

Purpose: To evaluate the risk of low-risk prostate cancer or prostate cancer that may benefit from surveillance in patients with a PSA level less than 10ng/ml, a normal digital rectal examination (DRE) and a transrectal power Doppler sonography (PDS) without anomaly.

Patients and Methods: Two hundred and forty-three consecutive patients with a PSA level less than 10ng/ml and a DRE without anomaly had PDS-guided biopsies: 12 to 15 samples were systematically taken and echo-guided in the suspect areas. The PDS results were rated from 1 to 4: 1: normal, 2: slightly hypoechogenic avascular area in which the hypo-echogenicity disappears after compression by probe, 3: hypoechogenic avascular area, 4: hypoechogenic vascularised area with power Doppler sonography. Patients rated 3 or 4 were considered to be pathological. D'Amico's criteria were used to assess the risk of a biological recurrence after treatment and those of Dall'Era were used to select the patients that could benefit from active surveillance (AS). The PDS was considered to be a true positive if at least one biopsy was positive in the same sextant as the suspect image.

Results: In a prospective manner, 106 cancers were diagnosed that could be qualified as low-risk in 84% of the cases (89% with a normal PDS and 79% with an abnormal PDS). Sixty-nine percent of the cases could be subject to AS (86% of the normal PDS cases and 47% of the abnormal PDS cases; P< 0.001). The PDS was normal in 159 of the 243 patients (65%).

With a normal PDS, there was a 96% probability of not having a high-risk cancer. With an abnormal PDS, at least one biopsy was positive in 57% of the cases and the probability of having a significant cancer was 30% according to the Dall'Era criteria. A significant reduction was noted with a normal PDS, to 36% and 5%, respectively (VPN=95%) (P=0.015).

Conclusion: A normal PDS in patients presenting a PSA level less than 10ng/mL and a DRE without anomaly may be used to put off the indication for a biopsy in order to reduce their number as well as the risks of overtreatment for a latent cancer.

LIMITATIONS OF BASING SCREENING POLICIES ON SCREENING TRIALS: THE US PREVENTIVE SERVICES TASK FORCE AND PROSTATE CANCER SCREENING

Etzioni R, Gulati R, Cooperberg MR, Penson DM, Weiss NS, Thompson IM

Med Care, 23 December 2012; Epub ahead of print

Background: The US Preventive Services Task Force recently recommended against PSA screening for prostate cancer based primarily on evidence from the European Randomized Study of Screening for Prostate Cancer (ERSPC) and the US Prostate, Lung, Colorectal, and Ovarian (PLCO) cancer screening trial.

Objective: To examine limitations of basing screening policy on evidence from screening trials.

Methods: We reviewed published modeling studies that examined population and trial data. The studies (1) project the roles of screening and changes in primary treatment in the US mortality decline; (2) extrapolate the ERSPC mortality reduction to the long-term US setting; (3) estimate overdiagnosis based on US incidence trends; and (4) quantify the impact of control arm screening on PLCO mortality results.

Results: Screening plausibly explains 45% and changes in primary treatment can explain 33% of the US prostate cancer mortality decline. Extrapolating the ERSPC results to the long-term US setting implies an absolute mortality reduction at least 5 times greater than that observed in the trial. Approximately, 28% of screen-detected cases are overdiagnosed in the US vs. 58% of screen-detected cases suggested by the ERSPC results. Control arm screening can explain the null result in the PLCO trial.

Conclusions: Modeling studies indicate that population trends and trial results extended to the long-term population setting are consistent with greater benefit of PSA screening-and more favorable harm-benefit tradeoffs-than has been suggested by empirical trial evidence.

If you want to obtain an electronic copy of the full paper, it is located on the Medical Care website on the third page of the list of articles published online ahead of print.

http://journals.lww.com/lww-medicalcare/Abstract/publishahead/Limitations_of_Basing_Screening_Policies_on.99350.aspx

UPDATED TOOL NOW AVAILABLE TO PREDICT PROSTATE CANCER SPREAD

Prostate cancer experts at Johns Hopkins have developed an updated version of the Partin Tables, a tool to help men diagnosed with prostate cancer and their doctors to better assess their chance of a surgical cure. The updated tool, based on a study of more than 5,600 men treated at The Johns Hopkins Hospital from 2006 to 2011, is published in the 3 January 2013 issue of the *British Journal of Urology International.*

"The first thing most men want to know when they learn they have prostate cancer is their prognosis – whether it can be cured," says Alan W. Partin, MD, PhD, professor and director of Urology at the Johns Hopkins University School of Medicine, and creator of the Partin Tables. "The Partin Tables are a statistical model to show the probability that the cancer is confined to the prostate and therefore is likely to be cured with surgery," he says.

The model is based on a patient's PSA level, Gleason Score and clinical stage – the extent to which a tumor can be felt during a digital exam. Treatment decisions for prostate cancer are very complex and depend on a variety of factors, including whether the cancer is confined to the prostate or whether it has spread to the edge of the gland, seminal vesicles, lymph nodes or elsewhere in the body.

Data for the Partin Tables, first published in 1993, have been based on the outcomes for more than 20,000 men who underwent prostate removal (known as radical prostatectomy) at Johns Hopkins over the past three decades. This represents the third update of the data.

"Twenty years ago, before wide adoption of PSA for early detection, many men were diagnosed with prostate cancer after their cancer had spread. Today, the vast majority of men are diagnosed when the cancer is still confined to the prostate, giving them a much better chance of a cure with a surgical removal of the prostate," says Partin.

John B. Eifler, MD, the lead author of the article who worked with Partin on the revision, says the new Partin Tables show that certain categories of men who were previously not thought to have a good prognosis actually could be cured with surgery. "We now have a better understanding of intermediate risk and see that more men now fall into that category, instead of the higher risk group," says Eifler.

For example, men with a biopsy Gleason Score of 8 and above previously were not thought to be good candidates for surgery because of the likelihood that the cancer had spread. The new data show a higher probability of a cure with surgery even if a man's Gleason score is 8. Scores of 9 and 10 are still considered high risk, indicating that the cancer likely has spread.

The researchers also found that having a PSA level of 10 and above was a better cut-off for predicting the spread of disease compared to lower levels.

"The updated Partin Tables will significantly improve the ability of physicians to counsel patients on the extent of their disease and help them make treatment decisions, such as whether surgery is warranted and, if so, whether lymph nodes also should be removed during surgery," Partin says. Other treatment options could be considered if there is a high probability that the cancer has spread.

To access the updated Partin Tables, go to http://urology.jhu.edu/prostate/partintables.php.

Science Daily, 3 January 2013

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The blue ribbon is the universal symbol for *Prostate Cancer Awareness*

HOW PROSTATE CANCER THERAPIES COMPARE

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assistant professor of urology and epidemiology and biostatistics in the UCSF Helen Diller Family Comprehensive Cancer Center.

Treatment for localized prostate cancer often varies dramatically from one treatment center to another. As Cooperberg put it, one man may have RP, while someone across town with a very similar tumor may have RT, and a third may undergo AS. All of the treatment regimens may be equally successful.

"There is very little solid evidence that one [approach] is better than another," said Cooperberg. The motivation for the new study, however, was that there are also few data examining the differences in terms of cost-effectiveness – the price to the health care system for every year of life gained, with adjustment for complications and side effects of treatments.

The new study was the most comprehensive cost analysis ever that compared costs and outcomes of the various types of treatment, which ranged from $19,901 for robot-assisted RP for low-risk disease, to $50,276 for combined modality RT for high-risk disease.

Science Daily, 4 January 2013

CPCC PHONE NUMBER & E-MAIL ADDRESS

For more information concerning CPCC or its programs and services, you can call us at (707) 786-7009 or send us an E-mail at cpcc@prostatecalif.org.

CPCC HELPLINE

This service is available for families and significant others of men who have been newly diagnosed with prostate cancer, are undergoing treatment or have suffered recurrent disease. Members of CPCC provide this service and are available to respond to your inquiries 7 days a week between 10:00 AM and 10:00 PM. You may call:

Stan Rosenfeld	(415) 459-4668
Erlinda Patterson (Spanish)	(909) 754-8392

CPCC WEBSITE

Go to our website <www.prostatecalif.org> for our calendar of events, legislative page, support group meetings and lending library. You can also access copies of past issues of CPCC News in PDF or Word format. There are direct links to other websites including current NCI trials.

CPCC publishes all major events in bi-monthly newsletter (February, April, June, August, October and December). We need your notice by the 9th of the month before printing. E-mail Stan Mikkelsen at cpcc@prostatecalif.org.

"YOUR CONTRIBUTIONS MAKE OUR WORK POSSIBLE"

Enclosed is my gift of $_____. **Mail to:** CPCC, 6709 La Tijera Blvd, Suite 473 Los Angeles, CA 90045

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